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| APPLICATION NO.                          | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|--|-----------------|----------------------|---------------------|-----------------|
| 10/022,187                               | 12/13/2001      | David Cole           | 019                 | 1041            |
| 32746                                    | 7590 10/19/2004 |                      | EXAMINER            |                 |
| HOEKENDIJK & LYNCH, LLP<br>P.O. BOX 4787 |                 |                      | PANTUCK, B          | RADFORD C       |
| BURLINGAME, CA 94011-4787                |                 |                      | ART UNIT            | PAPER NUMBER    |
|  |                 |                      | 3731                |                 |

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| · •   | Application No.   | Applicant(s) |  |  |  |  |
|---|---|--------------|--|--|--|--|
| Office Action Summan  | 10/022,187 /  | COLE ET AL.  |  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit     |  |  |  |  |
|   | Bradford C Pantuck  | 3731         |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |   |              |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |              |  |  |  |  |
| Status  |   | ·            |  |  |  |  |
| 1) Responsive to communication(s) filed on <u>08/02</u>   | 1) Responsive to communication(s) filed on 08/02/2004.  |              |  |  |  |  |
| 2a)⊠ This action is <b>FINAL</b> . 2b)□ This  | This action is <b>FINAL</b> . 2b) This action is non-final.   |              |  |  |  |  |
| 3) Since this application is in condition for allowan   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is |              |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.   |   |              |  |  |  |  |
| Disposition of Claims   |   |              |  |  |  |  |
| 4) Claim(s) <u>1-6</u> is/are pending in the application.   |   |              |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |   |              |  |  |  |  |
| 5) Claim(s) is/are allowed.   |   |              |  |  |  |  |
| 6)⊠ Claim(s) <u>1-6</u> is/are rejected.  | 6)⊠ Claim(s) <u>1-6</u> is/are rejected.  |              |  |  |  |  |
| 7) Claim(s) is/are objected to.   |   |              |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or   | election requirement.   |              |  |  |  |  |
| Application Papers  |   |              |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner.   |   |              |  |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  |   |              |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |              |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |   |              |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |              |  |  |  |  |
| Priority under 35 U.S.C. § 119  |   |              |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:  |   |              |  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |   |              |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |   |              |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage   |   |              |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).   |   |              |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.  |   |              |  |  |  |  |
| Attachment(s)   |   |              |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)   |   |              |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date   |   |              |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application (PTO-152)  6) Other:  |   |              |  |  |  |  |

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### **DETAILED ACTION**

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 1. Claims 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S.

  Patent No. 4,889,120 to Gordon et al. Gordon discloses forming an anastomosis

  [Column 7, lines 15-27] between two blood vessels [Column 6, lines 56-57; Column 5, lines 59-60] to place their lumens in fluid communication. One of ordinary skill in the bypass surgery art knows that Gordon is intending to place lumens (the inside cavities of respective tubes) in fluid communication with each other because he intends to use his apparatus to form an "end-to-side" connection between vessels

  [Column 7, line 23].

Gordon uses magnetic force to couple the two vessels [Column 2, lines 1-3]. Specifically, Gordon discloses microscopic particles, which have magnetic properties. He introduces these magnetic particles into the edges of the vessels that are to be connected [Column 2, lines 37-45].

Each microscopic particle can be considered a "component." Therefore, inevitably, as sum of the magnetic force of microscopic particles on the first vessel attracts the microscopic particles on the second vessel, one particle from the first vessel will be magnetically pulled to contact a particle on the second vessel.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by
 U.S. Patent No. 6,352,543 B1 to Cole. Cole discloses in Fig. 9A (see also Column 7,
 lines 8-24) the anastomosis device and arrangement as claimed by Applicant.

The applied reference has a common assignee and a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over
   U.S.S.R. Inventors' Certificate No. 1,179,978 to Myshkin in view of U.S. Patent No.
   4,889,120 to Gordon. Although the Myshkin reference is in Russian, an English

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abstract has been included with the document. Also, U.S. Patent No. 5,690,656 to Cope et al. describes what is disclosed in the Myshkin reference in Column 1, lines 31-59.

Myshkin discloses employing magnetic rings (1,2) to form an anastomosis between hollow organs of the digestive tract [see Abstract]. The magnetic rings are shown clearly in Figure 1 and the anastomosis is shown clearly in Figure 2.

Myshkin's configuration is also shown in Figure 3 of U.S. Patent No. 5,690,656 to Cope et al. As demonstrated by these references, such a configuration—one in which two magnetic rings are used for an anastomotic procedure—is well known in the medical art.

However, Myshkin's magnet assembly is capable of being configured in may different ways. Applicant's oft repeated language "configured to be..." is quite a broad limitation. For example, Myshkin's assembly is capable of being configured to be attached to the outside of each vessel, as shown in Attachment II.

Gordon discloses securing magnetic materials to the walls of vessels and provides a motivation for using an adhesive to secure them to vessels. Gordon teaches that in order to enhance the magnetic connection between biological vessels one ought to use an adhesive in conjunction with the magnets [Column 6, lines 44-48]. Applicant should note that although Gordon does not disclose the same configuration (rings located inside of the lumens of the vessels) as Myshkin, he does disclose the principle of coating magnets with an adhesive glue. Therefore, it would have been obvious to one having ordinary skill in the vessel connecting art at the time of the invention to

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apply an adhesive glue liberally to all the surfaces of Myshkin's rings (1,2) in order to more firmly secure the anastomosis connection, as taught by Gordon.

#### Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,632,229 B1 to Yamanouchi

# Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 24 of U.S. Patent No. 6,652,540 to Cole et al., Claims 1-3 of U.S. Patent No. 6,352,543 B1 to Cole, and Claim 23 of U.S. Patent No. 6,719,768 B1 to Cole et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because Figure 9A (and the

corresponding description in each respective specification) in each patent obviates

Applicant's claimed configuration.

The subject matter claimed in the instant application is fully disclosed in the above mentioned patents and is covered by the patents since the patent and the application are claiming common subject matter.

7. Claims 1-6 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/022187 and claim 1 of copending Application No. 10/090199. Although the conflicting claims are not identical, they are not patentably distinct from each other because Figure 6A of the first mentioned copending Application and Figure 9A of the second copending Application obviates the difference between the respective claims of the two copending Applications and the current Application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period,

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then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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# Response to Arguments

Applicant's arguments filed 08/02/2004 have been fully considered but they are not persuasive. Examiner agrees that USSR Inventor's Certificate Patent No. SU 1179978 to Myshkin et al. (English translation included with this office action) does not show the two magnets touching each other, while securing the two vessels to form an anastomosis, as argued by Applicant on page 1 of "Remarks/Arguments" of 08/02/2004. However, if one were to glue ring 1 to the lumen of the vessel 12 and one were to glue ring 2 to the lumen of vessel 11, the magnetics of ring 1 and ring 2 would cause them to be pulled towards each other, and touch each other. Such an arrangement would hold the two vessels against each other and form an anastomosis. Although Myshkin teaches that an arrangement that will cause necrosis of the vessels and "movement of the rings along the gastrointestinal tract" (last line of English translation), he *does not teach against* gluing the rings to the lumens. Thus, the rings (1 and 2) are capable of contacting one another, while forming an anastomosis (with the aid of glue) [see Attachment II].

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (703) 308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP October 8, 2004

ANHTUANT. NGUYEN PRIMARY EXAMINER